REMARKS

Claims 1–3 and 7–9 are pending with claims 8 and 9 withdrawn and claims 4–6 canceled without prejudice or disclaimer. Claims 10–23 are added by this paper.

Claim Amendments

The claims have been amended to correct typographical errors (for *e.g.* claim 2) and to use language in accordance with conventional U.S. practice. It is submitted that the claim amendments do not add new matter.

Support for the newly added claims can be found in the specification, as originally filed. For example, support for new claims 10-20 can be found at page 5 and 6; support for new claims 21-23 can be found at page 4, lines 14-25 and at page 11, lines 1-28.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-2 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. In addition, claims 1-7 currently stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to provide a written description. Applicants respectfully traverse.

It is alleged at page 3 of the Office Action that "the specification does not provide enablement for 7-12 residues of these amino acids". Apparently, the Examiner is asserting that the combined length of these residues would exceed the 500-2500 pm recitation in claim 1. Applicants respectfully submit that the size feature recited in claim 1 is not placed on the entire peptide compound, but rather on the α-aminocarboxylic acid residues which make up R^1. Withdrawal of the rejection is respectfully requested.

Furthermore, an application disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph 35 U.S.C. § 112, unless there is reason to doubt the objective truth of statements contained therein

relied on for enabling support. See, e.g., *Marzocchi, In re Brana, 51 F.3d 1560,* 34 USPQ2d 1436 (Fed. Cir. 1995), and *Fiers v. Revel, 984 F.2d 1164,* 24 USPQ2d 1601 (Fed. Cir. 1993). So, to establish non-enablement, an Examiner can not merely allege that some aspect is non-enabled, as in the instant rejection. The Examiner must present reasons why one would doubt that these compounds can be formed from the starting materials.

It is further alleged at page 4 of the Office Action that the specification fails to provide a written description of the salts and solvates claimed in the instant application. In dispensing the rejection, the Examiner uses Vippagunta et al. (*Advanced Drug Delivery Review*, **vol. 48**, pages 3-26, **2001**) to allege that the formation of solvates is a complicated process and one that is not properly disclosed in the specification.

To satisfy the written description requirement, all that is needed is forth the disclosure to "reasonably convey" that applicants' had possession of the claimed subject matter at the time of filing. See, e.g., *In re Kaslow,* 217 USPQ 1089 (Fed. Cir. 1982). *Ipsis verbis* disclosure is not required. See, e.g., *Fujikawa v. Wattanasin,* 39 USPQ 1895 (Fed. Cir. 1996). In addition, the burden of establishing that a claimed invention is not described in the disclosure rests on the PTO. See, for example, *In re Wertheim*, 191 USPQ 90 (CCPA 1976). Merely asserting a lack of literal support is not enough. (*Wertheim* at page 98).

Applicants' specification clearly conveys possession of the concept of pharmaceutically acceptable salts and solvates. See, e.g., page 1, lines 24-25 and the texts bridging pages 16-17. The rejection fails to present any rationale as to why such disclosure does not reasonably convey possession of the claimed subject matter.

Moreover, contrary to the implication in the rejection, the pharmaceutical art clearly does recognize the formation of salts and solvates of pharmaceutically active substances such as those claimed by the instant invention. For example, starting from a peptide compound, one of ordinary skill in the art would be able to employ the teaching of Vippagunta et al. and others to perform routine experimentation and successfully arrive at the claimed salts and solvates. Furthermore, it is well-established that the production of salts and solvates of existing compounds is both a routine and a trivial task for one of ordinary skill, provided that he/she is equipped with necessary compounds (solvents, acids etc.) and conditions (pH, temperature etc.) for carrying out such a process. Representative examples of such methods are amply provided

throughout the specification. For example, see lines 22-40 at page 16; lines 1-25 at page 17; and Example 1. Also see the table at page 25.

In view of the above remarks, withdrawal of the rejections Under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Rejection Under 35 U.S.C. § 112, second paragraph

The rejections, not specifically addressed herein, are moot in view of the claim amendments. Withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. § 102 (b)

The rejection of claims 1 and 2 as being anticipated by Pierschbacher et al. (*PNAS*, **vol. 81**, pages 5985-5988, **1984**) is respectfully traversed.

Pierschbacher discloses a tetrapeptide sequence, Arg-Gly-Asp-Ser, as the minimal structure that is utilized in recognition of fibronectin by cells. It is disclosed that among these four amino-acid residues, the tri-peptidic sequence Arg-Gly-Asp (RGD) is crucial for recognition, while substitution of the Ser residue with another amino acid residue may also result in a biologically active tetrapeptide. See ABSTRACT section of Pierschbacher et al. Table 1 and Table 3 of the cited reference provide several examples of these peptides containing the conserved RGD sequence. It is clear that from Pierschbacher's examples and the references in Table 2 that the cited disclosure is limited to *linear peptides* (i.e. a chain comprising four or more amino acid residues that are linked covalently in a linear fashion). Pierschbacher does not disclose or teach other variations, such as cyclic peptides of the instant invention.

The Examiner's interpretation of "derivatives" as recited in the prior version of claim 1 is incorrect. Whether a compound of claim was called a derivative or not, claim 1 still recited that the compound was of formula I and thus was cyclic and contained more than four amino acid residues. In any event, to facilitate prosecution, claim 1 now refers to the peptide compound of formula I.

Since all material elements of the claims are not disclosed in the cited reference, the teachings of Pierschbacher cannot anticipate the peptide compounds claimed by the instant invention. Hence, withdrawal of the rejection is respectfully requested.

No fee is believed to be due with this response, however, the Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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